

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NUMBER: 10/712,795
FILING DATE: 11/13/2003
FIRST NAMED INVENTOR: Rosanne Crooke
ART UNIT: 1633
EXAMINER NAME: Janet L. Epps Ford
ATTORNEY DOCKET NUMBER: DOC-0216US (ISIS.003CP1)
TITLE: Antisense modulation of apolipoprotein B expression

MAIL STOP AMENDMENT
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

SIR:

Enclosed herewith are PTO Forms PTO/SB/08A and PTO/SB/08B listing references for consideration by the Examiner. Copies of any foreign patent documents and non-patent literature cited therein are enclosed. This Supplemental Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(c). Accordingly, attached hereto is the fee set forth under 37 C.F.R. § 1.17(p).

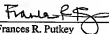
Applicants make of record the following related co-pending, commonly owned U.S. patent applications, each of which is cited on the enclosed Form PTO/SB/08A:

U.S. Patent Application No. 09/920,033, filed August 1, 2001, published as US 2003/0087853,
U.S. Patent Application No. 10/147,196, filed May 15, 2002, published as US 2003/0215943,
U.S. Patent Application No. 10/920,612, filed August 17, 2004, published as US 2005/0009088,
U.S. Patent Application No. 11/123,656, filed May 5, 2005, published as US 2006/0009410,
U.S. Patent Application No. 11/124,020, filed May 5, 2005, published as US 2005/0287558, and
U.S. Patent Application No. 11/200,710, filed August 10, 2005, published as US 2006/0035858.

It is requested that the information disclosed herein be made of record.

Respectfully Submitted,

Dated: June 27, 2006

By: 
Frances R. Putkey
Registration No.: 57,257
Isis Pharmaceuticals, Inc.
1896 Rutherford Road
Carlsbad, CA 92008

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT****(Not for submission under 37 CFR 1.99)**

Application Number	10712795
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Attorney Docket Number	DOC-0216US

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1					

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U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20030087853	A1	2003-05-08	Crooke et al.	
	2	20030215943	A1	2003-11-20	Crooke et al.	
	3	20050009088	A1	2005-01-13	Crooke et al.	
	4	20050287558	A1	2005-12-29	Crooke et al.	
	5	20060009410	A1	2006-01-12	Crooke et al.	

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6	20060035858	A1	2006-02-16	Geary et al.	
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FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	9918986	WO	A1	1999-04-22	Trustees of Columbia University		<input type="checkbox"/>
	2	0911344	EP	B1	2004-03-03	Fujirebio Inc.		<input type="checkbox"/>
	3	0112789	WO	A2	2001-06-14	Baylor College		<input type="checkbox"/>
	4	0130354	WO	A1	2001-05-03	Thomas Jefferson University		<input type="checkbox"/>

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	BOREN, J. et al., "A Simple and Efficient Method for Making Site-directed Mutants, Deletions, and Fusion of Large DNA Such as P1 and BAC Clones," Genome Res. (1996) 6:1123-1130.	<input type="checkbox"/>
	2	BRANCH, A. D., "A good antisense molecule is hard to find," TIBS (1998) 23:45-50.	<input type="checkbox"/>

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3	DAVIDSON, N. O. et al., "Apolipoprotein B: mRNA Editing, Lipoprotein Assembly, and Presecretory Degradation," Annu. Rev. Nutr. (2000) 20:169-193.	<input type="checkbox"/>
4	DEEB, S. S., et al., "Chromosomal localization of the human apolipoprotein B gene and detection of homologous RNA in monkey intestine," Proc. Natl. Acad. Sci. USA (1988) 83:419-422.	<input type="checkbox"/>
5	FARESE, R. V., Jr. et al., "Knockout of the mouse apolipoprotein B gene results in embryonic lethality in homozygotes and protection against diet-induced hypercholesterolemia in heterozygotes," Proc. Natl. Acad. Sci. USA (1995) 92:1774-1778.	<input type="checkbox"/>
6	HAJJAR, K. A. et al., "The Role of Lipoprotein(a) In Atherogenesis and Thrombosis," Annu. Rev. Med. (1996) 47:423-442.	<input type="checkbox"/>
7	INNERARITY, T. L. et al., "Familial defective apolipoprotein B-100: Low density lipoproteins with abnormal receptor binding," Proc. Natl. Acad. Sci. USA (1987) 84:6919-6923.	<input type="checkbox"/>
8	KATAN, M. B. et al., "Characteristics of Human Hypo- and Hyperresponders to Dietary Cholesterol," Am. J. Epidemiology (1987) 125(3):387-399.	<input type="checkbox"/>
9	KIM, E. et al., "Genetically modified mice for the study of apolipoprotein B," J. Lipid Res. (1998) 39:703-723.	<input type="checkbox"/>
10	LAW, S. W. et al., "Human apolipoprotein B-100: Cloning, analysis of liver mRNA, and assignment of the gene to chromosome 2," Proc. Natl. Acad. Sci. USA (1985) 82:8340-8344.	<input type="checkbox"/>
11	MCCORMICK, S. P. A. et al., "Transgenic Mice Expressing Human ApoB95 and ApoB97," J. Biol. Chem. (1997) 272 (38):23616-23622.	<input type="checkbox"/>
12	NISHINA, P. M. et al., "Synthetic low and high fat diets for the study of atherosclerosis in the mouse," J. Lipid Res. (1990) 31:859-869.	<input type="checkbox"/>
13	SANDKAMP, M. et al., "Lipoprotein(a) is an Independent Risk Factor for Myocardial Infarction at a Young Age," Clin. Chem. (1990) 38(1):20-23.	<input type="checkbox"/>

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SEED, M. et al., "Relation of Serum Lipoprotein(a) Concentration and Apolipoprotein(a) Phenotype to Coronary Heart Disease in Patients with Familial Hypercholesterolemia," N. Engl. J. Med. (1990) 322(21):1494-1499.

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VESBY, G. et al., "Diverging Effects of Cholestyramine on Apolipoprotein B and Lipoprotein Lp(a)," Atherosclerosis (1982) 44:61-71.

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CHIN, A., "On the Preparation and Utilization of Isolated and Purified Oligonucleotides." Document purportedly located on a CD-ROM and contributed to the public collection of the Katherine R. Everett Law Library of the University of North Carolina on March 14, 2002.

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EGGERMAN, T. L. et al., "Use of Oligonucleotides to Target Nucleic Acid Sequences Encoding Apolipoprotein B to Decrease Serum Apolipoprotein B and Cholesterol Levels," Federal Register (2000) 65(110).

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If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature

Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

- ☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

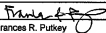
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- ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

- ☐ See attached certification statement.
- ☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature		Date (YYYY-MM-DD)	2008-06-27
Name/Print	Frances R. Putkey	Registration Number	57,257

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**